the terms hereof. The Commission intends to monitor the procedures and practices followed pursuant hereto, including through review of the results of audits of registrants handling bunched orders. Based thereon, the Commission may provide further guidance as appropriate.

Dated: May 5, 1997.

By the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–12161 Filed 5–8–97; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 95F–0163]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of high-purity furnace black as a colorant for polymers intended for use in contact with food. This action is in response to a petition filed by Cabot Corp.

DATES: The regulation is effective May 9, 1997. Submit written objections and requests for a hearing by June 9, 1997. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 178.3297(e), effective May 9, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 20, 1995 (60 FR 37452), FDA announced that a food additive petition (FAP 5B4464) had been filed by Cabot Corp., 75 State St., Boston, MA 02109–1806. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of high-purity furnace black as a colorant for polymers intended for use in contact with food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of polynuclear aromatic hydrocarbons (PAH's), which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as polynuclear aromatic hydrocarbons in this instance, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additive anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA concludes that the additive, high-purity furnace black, is insoluble in common solvents, including aqueous and fatty foods. As a consequence, there is no potential for significant levels of migration of the furnace black to contacted food (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that because there is no potential for significant levels of migration of furnace black to contacted food, there are no concerns regarding the safety of the additive itself.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by PAH's, the carcinogenic chemicals that may be present as impurities in the additive. The risk evaluation of PAH's has two aspects: (1) Assessment exposure to the impurities from the intended use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. Polynuclear Aromatic Hydrocarbons

FDA has estimated the worst-case exposure to PAH's from the petitioned use of the additive as a colorant in polymers to be no greater than 0.001 parts per billion (ppb) in the daily diet (3 kilograms (kg)), or 3 nanograms per person per day (ng/person/day). Further, the dietary concentration of benzo[a]pyrene, one member of the PAH family, was estimated to be no greater than 0.01 parts per trillion in the daily diet (3 kg), or 30 picograms /person/day (Ref. 1).

PAH's occur as a mixture of compounds; the toxicity of these compounds varies, and some members of the family have been shown to be carcinogenic in animal studies. In assessing the upper-bound limit of lifetime human risk, FDA prefers to use actual toxicity data for the specific contaminants. However, in the absence of such data, the agency believes that using the toxicity of one of the most potent cogeners in a family of contaminants will ensure that the upper-bound limit of lifetime human risk will not be underestimated. For this risk estimate, FDA has made the ''worst-case'' assumption that all PAH's in the additive have the same carcinogenic potency as benzo[a]pyrene, a member of the PAH family that current data show to be one of the most potent carcinogens of this group.

The agency used data from a carcinogenesis bioassay on benzo[a]pyrene, conducted by H. Brune et al. (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The

authors reported that the test material caused treatment-related benign forestomach tumors or esophageal tumors in male rats.

Based on the estimated worst-case exposure of 3 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the additive is 9×10^{-8}, or less than 1 in 10 million (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate and the carcinogenic potency of PAH's in the additive, the actual lifetime-averaged individual exposure to PAH's is likely to be substantially less than the worst-case exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to PAH's would result from the petitioned use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of PAH's present as impurities in the additive. The agency finds that specifications are necessary to ensure that the risk from PAH's resulting from the proposed use of high-purity furnace black in food-contact applications is insignificant and that use of the additive is safe. Therefore, the regulations set forth in this document prescribe that high-purity furnace black shall not contain total PAH's in excess of 0.5 parts per million and shall not contain benzo[a]pyrene in excess of 5.0 ppb.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive as a colorant in polymers is safe; (2) the additive will achieve its intended technical effect; and (3) that therefore, the regulations in § 178.3297 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 9, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch, FDA, to the Indirect Additives Branch, FDA, concerning ''FAP 5B4464 (MATS # 819 M2.0 & 2.1): Cabot Corp. petition, through their agent Keller and Heckman, dated 5–18–95. High-Purity Furnace Black as a Colorant for Polymers,'' dated April 2, 1996.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis, and S. Karger, New York, NY, pp. 24–33, 1985.

3. Brune, H., R. P. Deutsch-Wenzel, M. Habs, S. Ivankovis, and D. Schmahl, ''Investigation of the Tumorigenic Response to Benzo[a]pyrene in Aqueous Caffeine Solution Applied Orally to Sprague-Dawley Rats,'' *Journal of Clinical Research and Clinical Oncology*, 102:153–157, 1981.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning ''Estimation of the Upper-bound Lifetime Risk from Polynuclear Aromatic Hydrocarbons (PAH's) in High-Purity Furnace Black (HPFB): subject of Food Additive Petition No. 5B4464 (Cabot Corp.),'' dated May 9, 1996.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
High-purity furnace black (CAS Reg. No. 1333–86–4) containing total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled ''Determination of PAH Content of Carbon Black,'' dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.	For use at levels not to exceed 2.5 percent by weight of the polymer.
* * *	* * * *

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12156 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Medicated Feed Applications; Semduramicin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for revised assay limits for Type C medicated semduramicin chicken feed to 80 to 110 percent of labeled claim.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 140–940, which provides for revising the assay limits for Type C medicated chicken feed containing Aviax™ (semduramicin sodium) from 85 to 110 percent of labeled claim to 80 to 110 percent. The supplemental NADA is approved as of April 8, 1997, and the regulations are amended in 21 CFR 558.4(d) to reflect the approval.

Revision of the assay limits for a Type C medicated feed is based on the evaluation of the assay procedure used to analyze the feed and analysis of the assays of those feeds. The initial assay limits were established based on the results of the method trial. Evaluation of the feeds used in the market support trials, comparable to commercial manufacturing operations, support a wider assay range. This action did not require reevaluation of the safety and effectiveness data supporting the original approval. Therefore, a freedom of information summary is not required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled ''Category I,'' in the entry for ''Semduramicin,'' in the last column by removing the assay limits ''85–110'' and adding in its place ''80–110.''

Dated: April 30, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–12257 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 898

[Docket No. 94N–0078]

Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a performance standard for electrode lead wires and patient cables. The agency is taking this action because it has determined that a performance standard is needed to prevent electrical connections between patients and electrical power sources. The final rule will substantially reduce the risk of electrocution from unprotected electrode lead wires and patient cables.

DATES: This regulation is effective August 7, 1997, except that § 898.14 (21 CFR 898.14) is stayed pending Office of Management and Budget (OMB) clearance for information collection. FDA will announce the effective date of § 898.14 in the **Federal Register**. Submit written comments on the information collection provisions of this final rule by July 8, 1997.